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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,055	11/16/1999	YOSHIHIRO USUDA	0010-1057-0	3806
22850	7590	09/09/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/441,055	<b>Applicant(s)</b> USUDA ET AL.	
	<b>Examiner</b> Christian L Fronda	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 11-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 31-40 are under consideration in this Office Action.

#### ***Claim Rejections - 35 U.S.C. § 101***

2. Claims 31-40 stand rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Applicants' arguments filed June 9, 2004, have been fully considered but are not persuasive. Applicants' position is that a method necessarily requires the "hand of man" and that the claimed invention is in full compliance with 35 U.S.C. § 101. The examiner respectfully disagrees for reasons of record as supplemented below.

The claims as written employ any bacterium deficient in any repressor of L-methionine biosynthesis system having enhanced intracellular homoserine transsuccinylase activity. The claims as written do not provide any indication of the "hand of man" giving any new forms, qualities, properties, or combinations thereof to the said bacterium deficient in any repressor of L-methionine biosynthesis system having enhanced intracellular homoserine transsuccinylase activity. The specification discloses genetic modifications to bacteria which is employed in the production of L-methionine (see Examples 1-5). The claims should be amended to recite the genetic modification to indicate the hand of the inventor. See MPEP 2105.

#### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

3. The enablement rejection of claims 31-40 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of Applicants' arguments filed June 9, 2004.

4. Claims 31-40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed June 9, 2004, have been fully considered but are not persuasive. Applicants' position is that specification provides detailed description of the repressor of L-methionine biosynthesis system and homoserine transsuccinylase of the claimed

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invention. The examiner respectfully disagrees for reasons of record as supplemented below.

The claims are not limited to the specific repressor, *metJ* encoding the E.coli repressor, as disclosed in the specification at p. 10, line 19 to p. 16, line 6. Instead the claims are genus claims that encompass any repressor of any sequence/structure of any enzyme/protein involved in L-methionine biosynthesis. Neither the specification nor the general knowledge of those skilled in the art provide evidence of any partial structure which would be expected to be common to the members of the genus. The specification does not provide a description of additional representative repressors of any sequence/structure of any enzyme/protein involved in L-methionine biosynthesis as encompassed by the genus claims.

The claims are not limited to the specific E. coli homoserine transsuccinylase disclosed at p. 16, line 8 to p. 20, line 7 comprising SEQ ID NO: 26, SEQ ID NO: 26 where arginine is replaced with cysteine at position 27, SEQ ID NO: 26 where isoleucine is replaced with serine at position 296, or SEQ ID NO: 26 where proline is replaced with leucine at position 298. Furthermore, the specification only describes the *metK*, *metB*, and *metL* genes from E.coli. Instead the claims are genus claims that encompass any homoserine transsuccinylase of any sequence/structure that is enhanced by any genetic modification. Neither the specification nor the general knowledge of those skilled in the art provide evidence of any partial structure which would be expected to be common to the members of the genus. The specification does not provide a description of additional homoserine transsuccinylases of any sequence/structure made by any genetic modification as encompassed by the genus claims.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

### ***Conclusion***

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

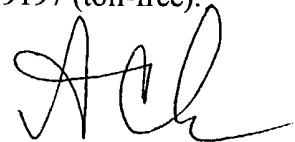
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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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